

REMARKS

Upon entry of the present amendment, claims 11-22 will be pending. New claims 17-22 are added and are fully supported by the instant application as filed. No new matter has been added.

The present reply is being filed with a Request for Continued Examination (RCE).

Rejection Under 35 U.S.C. § 103(a)

Claims 11-16 have been rejected for alleged obviousness over U.S. Pat. No. 5,712,295 to Mencke, *et al.* ("the U.S. Mencke patent") in view of WO 96/38165 to Mencke, *et al.* ("the Mencke publication") and U.S. Pat. No. 4,199,569 to Chabala, *et al.* ("the Chabala patent"). In particular, Office has contended that "it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the claimed invention was made to treat both endoparasitic and ectoparasitic infections with avermectins in combination with another endoparasitic agent such as those disclosed by [the Mencke patent] because the results achieved by said treatment would have been predictable" (2/10/09 Office Action at page 3, first paragraph). For alleged support of its contention, the Office cites the case of *In re Kerkhoven*, 626 F.2d 846, 850 (C.C.P.A. 1980), in which it was held that "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be useful for the very same purpose". However, the holding of *In re Kerkhoven* is not applicable to the presently cited art or the instant claims against which such art is cited, and in fact a *prima facie* case of obviousness has not been presented.

There is no combination of three cited prior art references to which *In re Kerkhoven* can be said to properly apply in order to support a *prima facie* case of obviousness. The Office premises the rejection of the pending claims on the alleged fact that because Mencke discloses that avermectins are effective against endoparasites, and the Chabala patent discloses that avermectins are effective against ectoparasites, "it would have been *prima facie* obvious . . . to use avermectins to treat both endo[parasitic] and ectoparasitic infections in combination with additional endoparasitic agent" (2/10/09 Office Action at page 3, last full

paragraph). However, the holding of *In re Kerkhoven* does not apply to the posited combination of the Mencke publication and the Chabala patent, at least because the two references cannot be said to teach “two compositions each of which is taught . . . to be useful for the same purpose”, and because the resulting combination would not be said “to be useful for the very same purpose”, as required by that court decision. More specifically, while the Mencke publication discloses compositions that are said to be effective against *endoparasites*, the Chabala patent discloses compositions that are said to be useful for a *different* purpose, *i.e.*, for treatment against *ectoparasites*. Likewise, any combination of the compounds of the Mencke publication with those of the Chabala patent would not “form a third composition to be useful *for the very same purpose* [as the constituent compounds]”, because the resulting “third” composition would not be for treatment of *only endoparasites* and would not be for treatment of *only ectoparasites*. Thus, the case of *In re Kerkhoven* does not apply to the posited combination of the Mencke publication and the Chabala patent, and as no other objective evidence or reasoning has been presented by the Office in support of its contention, a *prima facie* case of obviousness cannot said to exist.

Furthermore, even if one were to combine the respective teachings of the Mencke publication and the Chabala patent (a point not conceded by Applications), any composition that resulted from the combination of the compounds taught by the Mencke publication and the compounds taught by the Chabala patent would not be suitable for combination in accordance with *In re Kerkhoven* with the compounds that are said to be taught by the Mencke patent (*i.e.*, agonists and antagonists of the nicotenergetic acetyl-choline receptors), because the composition resulting from the Mencke publication / Chabala patent combination would not involve a composition that is “useful for the same purpose” as the compounds of the Mencke patent; the former would be useful for treatment of *both endo- and ectoparasites*, whereas the latter discloses compounds that are said to be useful for a *different* purpose, *i.e.*, for treatment of *only endoparasites*.

Therefore, the case of *In re Kerkhoven* does not apply to any possible combination of the Mencke publication and the Chabala patent with the Mencke patent. Moreover, even beyond *Kerkhoven*, there is logically no reason to add the teachings of Mencke patent to the base combination (ivermectins to treat both endo- and ecto-parasites) since the base combination is already effective against the same target (endo-parasites) as the Mencke patent

would be. Therefore, a *prima facie* case of obviousness cannot be said to exist, and the rejection of claims 11-16 under § 103(a) should be withdrawn.¹ See, e.g., *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references absent “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does*”) (citing *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

New Claims 17-22

New claims 17-22 have been added. Claim 17 is directed to method for treating an animal having both an endoparasitic infection and an ectoparasitic infection comprising identifying an animal having both an endoparasitic infection and an ectoparasitic infection, and administering to the identified animal a composition comprising the recited compounds. None of the prior art of record, either alone or in combination, teaches or suggests the claimed methods. For example, there is no teaching or suggestion to identify an animal having *both* an endoparasitic infection *and* an ectoparasitic infection, and then to administer a composition as claimed to the identified animal. Applicants submit that new claims 17-22 are therefore allowable.

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¹ Applicants also note that, with regard to the currently pending claims, the Office has not addressed the showing of indicia of nonobviousness as set forth in Applicants’ reply dated September 10, 2008. Applicants herein reiterate that the nonobviousness of the full scope of claims 11-16 is supported (in addition to the reasons provided above) by the unexpected results described in the declaration of Dr. Andreas Turberg filed with Applicants’ Reply dated September 10, 2008

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Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the pending Office Action and that the pending claims are in condition for allowance. Accordingly, an indication of allowability of the pending claims is respectfully requested.

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